DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-102 and CMS-105, and CMS-10631]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**:

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any

one of the following ways:

1. <u>Electronically</u>. You may send your comments electronically to http://www.regulations.gov. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. By regular mail. You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number _____

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at

http://www.cms.hhs.gov/PaperworkReductionActof1995.

- 2. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
- 3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see ADDRESSES).

CMS-102 and CMS-105 Clinical Laboratory Improvement Amendments of 1988 (CLIA)

Budget Workload Reports and Supporting Regulations

CMS-10631 The PACE Organization Application Process in 42 CFR Part 460

Under the PRA (44 U.S.C. 3501-3520) federal agencies must obtain approval from the

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. Type of Information Collection Request: Extension without change of a currently approved collection; Title of Information Collection: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Budget Workload Reports and Supporting Regulations; Use: We will use the collected information to determine the amount of Federal reimbursement for surveys conducted. Use of the information includes program evaluation, audit, budget formulation and budget approval. Form CMS-102 is a multi-purpose form designed to capture and record all

budget and expenditure data. Form CMS-105 captures the annual projected CLIA workload that the State survey agency will accomplish. Our regional offices also use the information to approve the annual projected CLIA workload. The information is required as part of the section 1864 agreement with the state. Form Numbers: CMS-102 and CMS-105 (OMB control number: 0938-0599); Frequency: Quarterly; Affected Public: State, Local, or Tribal Governments; Number of Respondents: 50; Total Annual Responses: 50; Total Annual Hours: 1,700. (For policy questions regarding this collection contact Jeffrey Pleines at 410-786-0684.)

2. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: The PACE Organization Application Process in 42 CFR Part 460; <u>Use</u>: Initial application requirements for the PACE program are currently set forth in 42 CFR 460.12 and in the PACE Manual, Ch. 17. Until recently, the submission of initial and SAE PACE applications and supporting information was in paper format. These applications are often hundreds of pages long, expensive to reproduce and transmit, and administratively inefficient, as staff reviewing different parts of the application are located in different physical locations and must receive hard copies of the material. However, beginning in 2016 and 2017, initial and SAE PACE applications, respectively, are being submitted via a new automated, electronic submission process. As with initial applications, an application also must be submitted for a PO that seeks to expand its service area and/or add a new service site, and with OMB approval, an automated application process will now also be required of PACE organizations submitting service area expansion applications. The collection specific to the application was approved by OMB for a 3-year period, which expires March 31, 2020. Approval is now requested for revisions to this currently-approved collection, which includes

modifications to the PACE application. Form Number: CMS-10631 (OMB control number:

0938-1326); Frequency: Once and occasionally; Affected Public: Private sector (Business or

other for-profits and Not-for-profit institutions) and State, Local, or Tribal Governments;

Number of Respondents: 730; Total Annual Responses: 84; Total Annual Hours: 4,626. (For

policy questions regarding this collection contact Stacy Davis at 410-786-7813.)

Dated: August 30, 2017

William N. Parham, III,

Director, Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

Billing Code:

4120-01-U-P

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